

## APPENDIX B

### Comparison of Amended Independent Claims to Original Claims

#### Claim 12:

AMENDED CLAIM	ORIGINAL CLAIM
<p>An <b>ultra high molecular weight polyethylene molded article</b> for production of a medical implant with improved wear resistance, said <b>article</b> comprising an <b>ultra high molecular weight polyethylene</b> crosslinked by irradiation, and then heated at a temperature from its melting point minus 50°C to its melting point plus 80°C.</p>	<p>An <b>orthopedic preformed material</b> for subsequent production of a medical implant with improved wear resistance, said preformed material is a <b>polyethylene</b> crosslinked by irradiation, and <b>thermally treated according to the method selected from the group consisting of: annealing and remelting.</b></p> <p>(See Shen Patent – Claim 1)*</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<p>1. All instances of <b>orthopedic preformed material</b> have been changed to <b>UHMWPE molded article</b>. “<b>UHMWPE molded article</b>” is described at col. 2, lines 43-46 of the specification:</p> <p style="padding-left: 40px;">“The invention relates to an ultra high molecular weight polyethylene (UHMWPE) molded article for artificial joints and to an artificial joint comprising the UHMWPE molded article....</p> <p>Thus the molded article corresponds to a preform on which further processing is to be carried out to provide components of artificial joints. As such it is an “<b>orthopedic preformed material</b>” for subsequent production of a medical implant with improved wear resistance.” “Orthopedic” because it is suitable for artificial joints (col. 1, lines 7-10). Subsequent production of a medical implant is described throughout. Wear resistance is noted at col. 2, lines 60-62. Also, “UHMWPE molded article” is used throughout the specification (col. 2, lines 44, 47, 56, and 60).</p> <p>2. The UHMWPE disclosed throughout the specification is a <b>polyethylene</b>. See, e.g., col. 2, line 44 of the specification. “<b>Polyethylene</b>” in original claims has been amended throughout all claims to “<b>ultra high molecular weight polyethylene</b>.”</p> <p>3. “<b>Annealing</b>” means “heating below the melting temperature.” “<b>Remelting</b>” means “heating above the melting temperature” (see Shen Patent, col. 4, lines 46-51). Applicants’ specification discloses heating from the mp minus 50°C (below the mp) to the mp + 80°C (above the melting point); see col. 4, lines 8-9; annealing and remelting are fully disclosed. See also Comparative Preparation Examples 1 to 3 for remelting (col. 5, lines 32-40), and see Preparation Example 7 for annealing (col. 5, lines 51-57). Thus, “<b>thermally treated according to the method selected from the group consisting of annealing and remelting</b>” has been changed to “<b>heated at a temperature from its melting point minus 50°C to its melting point plus 80°C</b>” and similar phrases throughout the claims.</p> <p>Further, the Shen Patent does not clarify why it uses the term “remelting” rather than “melting.” In this regard, “annealing” and “remelting” are defined at col. 4, lines 46-51 of the Shen Patent:</p> <p style="padding-left: 40px;">“In the preferred method, the crosslinked polymer is subjected to thermal treatment such as by remelting (i.e., heated above the melting temperature of the</p>	

\* Citations herein to corresponding claims in the Shen Patent (U.S. Patent No. 6,228,900) should not be interpreted as an admission or other representation that pending claims for which no citation is made are patentably distinct from the claims of the Shen Patent.

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crosslinked polymer) or annealing (i.e., heated at below the melting temperature of the crosslinked polymer) to produce the preformed polymeric composition.”

That is, remelting is defined as heating above the melting temperature, while annealing is defined as heating below the melting temperature. Although it is used many times, the term “remelting” is never further defined. The Shen Patent never explains why the term “remelting” is used rather than simply “melting.” Likely, given the focus of the Shen Patent on the processing of UHMWPE preforms, the reference to remelting is a reference to a prior melting step that takes place when UHMWPE resin powder is heated and consolidated to form the preform on which the irradiation and “remelting” is later carried out. Regardless, Applicants’ specification supports the amended claim language of “heating at a temperature from the melting point to 80°C above the melting point,” which has the same meaning and essentially the same scope as the “remelting” term of Shen et al.

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#### Claim 17:

AMENDED CLAIM	ORIGINAL CLAIM
<p>An <b>artificial joint</b>, with improved wear resistance, comprising a solid <b>ultra high molecular weight polyethylene</b> which has been previously crosslinked by irradiation and <b>then heated to a temperature from the melting point of the ultra high molecular weight polyethylene to 80°C above said melting point.</b></p>	<p>A <b>medical implant having a bearing surface</b> with improved wear resistance, said bearing surface comprising a solid <b>polyethylene</b> which has been previously crosslinked by irradiation and then <b>subsequently remelted.</b></p> <p>(See Shen Patent – Claim 9)</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"> <li>1. The specification deals with <b>artificial joints</b>, especially those requiring high strength because several times the patient's body weight is applied. Examples are hip and knee joints. Col. 1, lines 25-30. A person skilled in the art will recognize these are <b>medical implants</b>, which implicitly have a <b>bearing surface</b> that holds the weight applied by the body. See also col. 1, lines 8-9; col. 2, lines 43-46; col. 7, lines 45-59 for descriptions of artificial joints and col. 1, lines 19-25 for implanted artificial joint. Thus, "<b>medical implant having a bearing surface</b>" has been replaced with "<b>artificial joint.</b>"</li> <li>2. See Claim 12 notes regarding "<b>polyethylene.</b>"</li> <li>3. <b>Remelting</b> refers to heating the article at or above its melting temperature. (See Shen Patent, col. 4, lines 46-51). Applicants disclose such heating as being from the melting point to the melting point plus 80°C (col. 4, lines 8-12). And see Preparation Examples 1 to 3 col. 5, lines 24-27, where the irradiated sample was then melted completely at 200°C. Thus, all instances of <b>remelting</b> have been changed to "<b>heating said crosslinked article at a temperature from its melting point to its melting point plus 80°C.</b>" See, also, notes regarding Claim 12 for discussion of the meaning of the "remelting" term in the Shen Patent.</li> <li>4. "<b>Subsequently</b>" means heating occurs after irradiation. This is taught by the specification. See, e.g. col. 4, lines 4-5 ("Then, this slightly crosslinked UHMWPE molded article is heated up ... "). See, also, the preparation examples on col. 5 and 6. Thus, the term "<b>subsequently</b>" has been changed to "<b>then.</b>"</li> </ol>	

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#### Claim 27:

AMENDED CLAIM	ORIGINAL CLAIM
An <b>artificial joint</b> with improved wear resistance, comprising a solid <b>ultra high molecular weight polyethylene</b> which has been previously crosslinked by irradiation and then <b>heated at a temperature from its melting point minus 50°C to said melting point</b> .	A <b>medical implant having a bearing surface</b> with improved wear resistance, said bearing surface comprising a solid <b>polyethylene</b> which has been previously crosslinked by irradiation and subsequently <b>annealed</b> .  (See Shen Patent – Claim 27)
<b>SUPPORT FOR ELEMENT EQUIVALENCE</b>	
<ol style="list-style-type: none"><li>1. See Claim 17 notes regarding “<b>medical implant having a bearing surface.</b>”</li><li>2. See Claim 12 notes regarding “<b>polyethylene.</b>”</li><li>3. Annealed refers to heating the article to a temperature below its melting temperature. Applicants disclose such heating as being from “the melting point minus 50°C to the melting point.” (Col. 4, lines 8-12). Annealing is also disclosed as isothermal crystallization at a temperature of around 100°C to 130°C. (Col. 4, lines 58-60). Thus, all instances of “annealed” or “annealing” have been changed to “heating at a temperature of the melting point minus 50°C to said melting point.”</li><li>4. See Claim 17 notes regarding “<b>subsequently.</b>”</li></ol>	

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#### Claim 38:

AMENDED CLAIM	ORIGINAL CLAIM
<p>A method for increasing the wear resistance of <b>ultra high molecular weight polyethylene</b> comprising the steps of:</p> <p>(a) crosslinking said <b>ultra high molecular weight polyethylene</b> by irradiating it below its melting point; and then</p> <p>(b) heating the crosslinked <b>ultra high molecular weight polyethylene</b> at a temperature from its melting point minus 50°C to said melting point plus 80°C.</p>	<p>A method for increasing the wear resistance of a <b>preformed polyethylene</b> comprising the steps of:</p> <p>(a) crosslinking said polyethylene by irradiating it in a solid state; and</p> <p>(b) <b>subjecting the crosslinked polyethylene to thermal treatment which is selected from the group consisting of: annealing and remelting.</b></p> <p>(See Shen Patent – Claim 28)</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"> <li>1. See claim 12 notes regarding “<b>preformed polyethylene.</b>”</li> <li>2. “<b>In a solid state</b>” is recognized by a person skilled in the art to mean the polyethylene is irradiated below the melting temperature, and that its use here together with “remelting” is meant to specify an order of steps: i.e. first it is crosslinked below the mp, and then it is (re)melted. Those steps are disclosed in the specification. See col. 3, lines 44-46 stating that the temperature of the irradiation atmosphere “may be room temperature and also may be a higher temperature of not less than the crystal transition point (80°C).” Thus, the UHMWPE molded article is not melted. See also col. 5, lines 22-24 where the sample was irradiated at 25°C, where the sample is in its unmelted, solid state. Thus, all instances of <b>in its solid state</b> have been changed to <b>below its melting point.</b></li> <li>3. See Claim 12 notes regarding “<b>subjecting the crosslinked polyethylene to thermal treatment which is selected from the group consisting of: annealing and remelting.</b>”</li> </ol>	

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#### Claim 46:

AMENDED CLAIM	ORIGINAL CLAIM
<p>A method for increasing the wear resistance of an <b>ultra high molecular weight polyethylene molded article</b>, comprising the steps of:</p> <p>(a) crosslinking said article by irradiating it <b>below its melting point</b>; then</p> <p>(b) <b>heating</b> the crosslinked article at a <b>temperature from its melting point minus 50°C to its melting point plus 80°C</b>; and then</p> <p>(c) <b>cutting</b> the heated, crosslinked article.</p>	<p>A method for increasing the wear resistance of an <b>orthopedic preformed polyethylene polymer</b>, comprising the steps of:</p> <p>(a) crosslinking the preformed polyethylene polymer by irradiating it <b>in a solid state</b>;</p> <p>(b) <b>subjecting the crosslinked preformed polymer to thermal treatment which is selected from the group consisting of: annealing and remelting</b>; and</p> <p>(c) <b>removing the surface</b> of the thermally treated crosslinked preformed polymer wherein said polymer is polyethylene.</p> <p>(See Shen Patent – Claim 36)</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"> <li>1. See Claim 12 notes regarding “<b>orthopedic preformed polyethylene polymer.</b>”</li> <li>2. See Claim 12 notes regarding “<b>subjecting the crosslinked preformed polymer to thermal treatment which is selected from the group consisting of: annealing and remelting.</b>”</li> <li>3. See Claim 38 notes regarding “<b>in a solid state.</b>”</li> <li>4. <b>Removing the surface</b> is implicit in the disclosed process of making implants from the irradiated and heat treated (ultra high molecular weight) polyethylene) See e.g. col. 5, lines 4-6 (“the ... article ... obtained as described above can also be processed to a socket for artificial joints by cutting”; see col. 5, lines 11-13 “...UHMWPE molded article for artificial joints which is obtained by cutting...”; and see Example 1, col. 1, line 66 to col. 2, line 4). A person skilled in the art will recognize that processing and <b>cutting</b> the article necessarily involves removing the surface of the thermally treated polymer. All instances of <b>removing the surface</b> have been replaced with <b>cutting</b>.</li> </ol>	

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**Claim 53:**

AMENDED CLAIM	ORIGINAL CLAIM
<p>A method for increasing the wear resistance of an <b>ultra high molecular weight molded article</b>, comprising the steps of:</p> <p>(a) crosslinking said article by irradiating it <b>below its melting point</b>; and then</p> <p>(b) <b>heating</b> said crosslinked article <b>at a temperature from its melting point to its melting point plus 80°C</b>.</p>	<p>A method for increasing the wear resistance of a <b>preformed polymer</b>, comprising the steps of:</p> <p>(a) crosslinking said preformed polymer by irradiating it <b>in its solid state</b>; and</p> <p>(b) <b>remelting</b> said crosslinked polymer, said polymer being <b>polyethylene</b>.</p> <p>(See Shen Patent – Claim 43)</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"><li>1. See Claim 12 notes regarding “<b>preformed polymer</b>.”</li><li>2. See Claim 38 notes regarding “<b>solid state</b>.”</li><li>3. See Claim 17 notes regarding “<b>remelting</b>.”</li><li>4. See Claim 12 notes regarding “<b>polyethylene</b>.”</li></ol>	

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#### Claim 58:

AMENDED CLAIM	ORIGINAL CLAIM
An <b>ultra high molecular weight polyethylene molded article</b> made according to a method comprising the steps of: (a) crosslinking a starting <b>ultra high molecular weight polyethylene</b> by irradiating it <b>below its melting point</b> to form a crosslinked ultra high molecular weight polyethylene; and then (b) <b>heating</b> the crosslinked ultra high molecular weight polyethylene <b>at a temperature from its melting point minus 50°C to its melting point plus 80°C</b> ; wherein said <b>article</b> has improved wear resistance over untreated ultra high molecular weight polyethylene.	A <b>preformed polyethylene</b> made according to a method comprising the steps of: (a) crosslinking a starting <b>polyethylene</b> by irradiating it <b>in a solid state</b> to form a crosslinked polyethylene; and (b) <b>subjecting the crosslinked polyethylene to thermal treatment which is selected from the group consisting of: annealing and remelting</b> ; wherein said <b>preformed polyethylene</b> has improved wear resistance over untreated polyethylene.  (See Shen Patent – Claim 51)
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"><li>1. See Claim 12 notes regarding “<b>preformed polyethylene.</b>”</li><li>2. See Claim 38 notes regarding “<b>solid state.</b>”</li><li>3. See Claim 12 notes regarding “<b>subjecting the crosslinked polyethylene to thermal treatment which is selected from the group consisting of: annealing and remelting.</b>”</li></ol>	



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#### Claim 70:

AMENDED CLAIM	ORIGINAL CLAIM
An <b>ultra high molecular weight polyethylene article</b> made according to the method comprising the steps of: (a) crosslinking a starting <b>ultra high molecular polyethylene</b> by irradiating it <b>below its melting point</b> to form a crosslinked ultra high molecular weight polyethylene; and then (b) <b>heating the crosslinked polyethylene at a temperature from its melting point to it melting point plus 80°C.</b>	A <b>preformed polymer</b> made according to the method comprising the steps of: (a) crosslinking a <b>starting polymer</b> by irradiating it <b>in a solid state</b> to form a crosslinked polymer; and (b) <b>remelting</b> the crosslinked polymer, wherein said polymer is <b>polyethylene</b> .  (See Shen Patent – Claim 62)
<b>SUPPORT FOR ELEMENT EQUIVALENCE</b>	
<ol style="list-style-type: none"><li>1. See Claim 12 notes regarding “<b>preformed polymer</b>” and “<b>starting polymer.</b>”</li><li>2. See Claim 38 notes regarding “<b>in a solid state.</b>”</li><li>3. See Claim 17 notes regarding “<b>remelting.</b>”</li></ol>	

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#### Claim 75:

AMENDED CLAIM	ORIGINAL CLAIM
An <b>artificial joint component</b> made by the process comprising the steps of: (a) crosslinking an <b>ultra high molecular weight polyethylene below its melting point</b> ; then (b) heating the crosslinked polyethylene to a <b>temperature from its melting point minus 50°C to its melting point plus 80°C</b> ; and then (c) <b>processing</b> the crosslinked and thermally treated polyethylene to make an artificial joint component.	An implantable <b>load bearing component</b> made by the process comprising the steps of: (a) crosslinking a <b>preformed polyethylene in its solid state</b> ; (b) <b>subjecting the crosslinked polyethylene to thermal treatment selected from the group consisting of: annealing and remelting</b> ; and (c) <b>fashioning</b> the implantable bearing component from the crosslinked and thermally treated polyethylene.  (See Shen Patent – Claim 70)
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"><li>1. Hip joints and the like disclosed in the specification are inherently “load bearing components.” The specification tells how to make the load bearing components by irradiating and heat treating UHMWPE preforms (molded articles), and then processing (or fashioning) the implantable load bearing component (such as acetabular cup) e.g. by cutting. Thus, instances of <b>load bearing component and implantable bearing component</b> have been changed to <b>artificial joint component</b>.</li><li>2. See Claim 12 notes regarding “<b>preferred polyethylene</b>.”</li><li>3. See Claim 53 notes regarding “<b>in a solid state</b>.”</li><li>4. See Claim 12 notes regarding “<b>subjecting the crosslinked polyethylene to thermal treatment selected from the group consisting of: annealing and remelting</b>.”</li><li>5. “<b>Fashioning</b>” is understood as generic for acting on the preform to turn its shape into that of a final component ready to implant. Fashioning corresponds to molding, where a “compression-deformation mold with a die comprising a convex and concave portions” is used to process the article to a socket for artificial joints. See col. 5, lines 4-13. Therefore, instances of <b>fashioning</b> have been changed to <b>processing</b>.</li></ol>	

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#### Claim 85:

AMENDED CLAIM	ORIGINAL CLAIM
<p>An <b>artificial joint component</b> made by the process comprising the steps of:</p> <p>(a) crosslinking an <b>ultra high molecular weight polyethylene</b> by irradiating it in a solid state; then</p> <p>(b) heating said polyethylene to a temperature from around 100°C to 130°C for a period of from 1 hour to 20 hours; and then</p> <p>(c) <b>processing</b> the crosslinked and thermally treated polyethylene to make an artificial joint component.</p>	<p>A <b>product</b> made by the process comprising the steps of:</p> <p>(a) crosslinking a <b>preformed polymer</b> by irradiating it in a solid state;</p> <p>(b) <b>subjecting the crosslinked polymer to thermal treatment</b> selected from the group consisting of: <b>annealing and remelting</b>;</p> <p>(c) <b>removing the oxidized surface of the crosslinked polymer</b>; and</p> <p>(d) <b>fashioning the product</b> from the crosslinked and thermally treated polymer; wherein said polymer polyethylene.</p> <p>(See Shen Patent – Claim 80)</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<ol style="list-style-type: none"> <li>1. See Claim 12 notes regarding “<b>preformed polymer.</b>”</li> <li>2. The Claim as amended is focused on <b>annealing</b>. As discussed regarding Claim 27, <b>annealing</b> means heating below the melting temperature. In this regard, the specification discloses such heating, inter alia, as heating <b>from around 100°C to 130°C for a period of from 1 hour to 20 hours</b>. See specification, at col. 4, lines 57-60.</li> <li>3. See Claim 46 notes regarding “<b>removing the oxidized surface.</b>”</li> <li>4. See Claim 75 notes regarding “<b>fashioning the product.</b>”</li> </ol>	

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**Claim 104:**

AMENDED CLAIM	ORIGINAL CLAIM
<p>A method for making an ultra high molecular weight polyethylene (UHMWPE) article, for subsequent processing to make <b>an artificial joint</b>, comprising:</p> <p>(a) irradiating a raw article comprising UHMWPE; and then</p> <p>(b) heating said irradiated article to a temperature of from 50° C below the melting point of said article to 80° C above said melting point.</p>	<p>A method for making an ultra high molecular weight polyethylene (UHMWPE) article, for subsequent processing to make a <b>medical implant</b>, comprising:</p> <p>(a) irradiating a raw article comprising UHMWPE; and</p> <p>(b) heating said article to a temperature of from <b>about</b> 50° C below the melting point of said article to <b>about</b> 80° C above said melting point.</p>
SUPPORT FOR ELEMENT EQUIVALENCE	
<p>1. See Claim 17 notes regarding “<b>medical implant</b>.”</p>	

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#### Claim 114:

AMENDED CLAIM	ORIGINAL CLAIM
A method for making an ultra high molecular weight polyethylene (UHMWPE) article which is suitable for subsequent processing to make an <b>artificial joint</b> , so as to improve the wear resistance properties of said article, comprising: (a) irradiating a raw article comprising UHMWPE; and then (b) heating said irradiated article to a temperature of from about 50° C below the melting point of said article to 80° C above said melting point.	A method for making an ultra high molecular weight polyethylene (UHMWPE) article which is suitable for subsequent processing to make a <b>medical implant</b> , so as to improve the wear resistance properties of said article, comprising: (a) irradiating a raw article comprising UHMWPE; and (b) heating said article to a temperature of from <b>about</b> 50° C below the melting point of said article to <b>about</b> 80° C above said melting point.
<b>SUPPORT FOR ELEMENT EQUIVALENCE</b>	
1. See Claim 17 notes regarding “ <b>medical implant</b> .”	

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**Claim 122:**

AMENDED CLAIM	ORIGINAL CLAIM
<p>A method of making a component for an artificial joint comprising ultra high molecular weight polyethylene (UHMWPE), comprising:</p> <ul style="list-style-type: none"><li>(a) irradiating a raw article comprising UHMWPE;</li><li>(b) heating said irradiated article to a temperature of from 50° C below the melting point of said article to 80° C above said melting point; and then</li><li>(c) processing said article to make said component.</li></ul>	<p>A method of making a component for an artificial joint comprising ultra high molecular weight polyethylene (UHMWPE), comprising:</p> <ul style="list-style-type: none"><li>(a) irradiating a raw article comprising UHMWPE;</li><li>(b) heating said article to a temperature of from <b>about</b> 50° C below the melting point of said article to <b>about</b> 80° C above said melting point; and</li><li>(c) processing said article to make said component.</li></ul>
<b>SUPPORT FOR ELEMENT EQUIVALENCE</b>	
<p>1. Instances of “about” have been removed.</p>	

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#### Claim 130:

AMENDED CLAIM	ORIGINAL CLAIM
A method for making an ultra high molecular weight polyethylene (UHMWPE) article, for subsequent processing to make <b>an artificial joint</b> , comprising: (a) irradiating a raw article comprising UHMWPE; and then (b) heating said irradiated article to a temperature of from around 100° C to 130° C for a period of at least 1 hour.	A method for making an ultra high molecular weight polyethylene (UHMWPE) article, for subsequent processing to make a <b>medical implant</b> , comprising: (a) irradiating a raw article comprising UHMWPE; and (b) heating said article to a temperature of from <b>about 100° C to about 130° C</b> for a period of at least <b>about 1 hour</b> .
SUPPORT FOR ELEMENT EQUIVALENCE	
1. See Claim 17 notes regarding “ <b>medical implant</b> .”	

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#### Claim 139:

AMENDED CLAIM	ORIGINAL CLAIM
A method of making a component for an artificial joint comprising ultra high molecular weight polyethylene (UHMWPE), comprising: (a) irradiating a raw article comprising UHMWPE; and then (b) heating said irradiated article to a temperature of from around 100° C to 130° C for a period of at least 1 hour; and then (c) processing said article to make said component.	A method of making a component for an artificial joint comprising ultra high molecular weight polyethylene (UHMWPE), comprising: (a) irradiating a raw article comprising UHMWPE; and (b) heating said article to a temperature of from <b>about</b> 100° C to <b>about</b> 130° C for a period of at least <b>about</b> 1 hour; and (c) processing said article to make said component.
<b>SUPPORT FOR ELEMENT EQUIVALENCE</b>	
1. Instances of “ <b>about</b> ” have been removed.	